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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,105	12/04/2001	Thomas J. Slaga	Enlarged Prostate-CIP	3918

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EXAMINER
SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/004,105	Slaga et al.
Examiner	**Art Unit**
Phyllis G. Spivack	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-9 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Cooperation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1440.

Claims 1-9 are presented and represent all of the claims under consideration.

The disclosure is objected to for the following informality: A Brief Description of the Figures is required in the disclosure.

Appropriate correction is required.

Claim 5 is objected to under 37 CAR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim, in independent form. Intended use of a composition claim confers no patentable weight to the claim.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Considering the recitation in claim 1, "inhibiting the growth of cancerous and precancerous cell populations", it is unclear whether applicants intend to recite growths that are both cancerous and precancerous, or, one or the other. If Applicants contemplate the latter situation, then the term "and" should be replaced with "or".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Sukumaran et al., Indian J. Physiol. Pharmacol. (abstract).

Sukumaran teaches the administration of eugenol to inhibit tumor promotion. Both cancerous and precancerous cell populations would have reasonably been encompassed by Sukumaran's teaching.

Claims 6 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Mukhopadhyay et al., U.S. Patent 5,958,892.

Mukhopadhyay teaches a therapeutic agent comprising 2-methoxyestradiol to treat a tumor. See claim 1, column 30.

Claims 1,-3 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Liao et al., WO 99/22728.

Liao teaches the administration of eugenol to treat both cancerous (prostatic) and precancerous (prostatitis) cells comprising administering eugenol. See Table 3, pages 23-24 and claim 7, page 32.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Defeudis, F.V., WO 96/30012.

Defeudis teaches the administration of eugenol, an antioxidant, to treat hyperplasia, a condition often associated with precancerous cell populations. See page 4, line 33, page 5, line 12, and claims 38-41.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Sukumaran et al., Indian J. Physiol. Pharmacol.(abstract), and Mukhopadhyay et al., U.S. patent 5,958,892.

Sukumaran teaches the administration of eugenol to inhibit tumor promotion. Mukuhopadhyay teaches the administration of 2-methoxyestradiol to treat a tumor. Both references are directed to treating an abnormal growth of tissue resulting from uncontrolled, progressive multiplication of cells, but are not limited to cancerous cell populations. One skilled in the art would have been motivated to prepare a therapeutic agent comprising eugenol and 2-

methoxyestradiol to treat both cancerous and precancerous cell populations in view of the combined teachings of Sukumaran and Mukhopadhyay. Such would have been obvious in the absence of evidence to the contrary because it is generally *prima facie* obvious to use in combination two or more ingredients that have previously been used separately for the same purpose to form a third composition useful for that same purpose. In re Kerkhoven 205 USPQ 1069 (CCPA 1980).

Obviousness does not require absolute predictability but only the reasonable expectation of success. Specific statements in the references themselves that would spell out the claimed invention are not necessary to show obviousness. Questions of obviousness involve not only what the references expressly teach, but what they would collectively suggest to one of ordinary skill in the art.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

October 6, 2002

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER